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NRx Pharmaceuticals, Lotus Pharmaceuticals and Alvogen Inc. Announce Collaboration to Develop and Commercialize NRX-101

- *NRx Pharmaceuticals, Lotus Pharmaceuticals, and Alvogen to collaborate on the further development and commercialization of NRX-101 for suicidal treatment-resistant bipolar depression (S-TRBD) for global markets*
- *Lotus Pharmaceuticals will acquire worldwide rights for NRX-101 for S-TRBD and will be responsible for commercialization of NRX-101 in markets outside the US through Lotus's direct presence in certain Asian markets or through their export division, which currently has partnerships in numerous markets, including in Europe, Japan, China, Australia and Latin America*
- *Alvogen, through its CNS focused Almatica® division, will be responsible for U.S. commercialization of NRX-101*
- *NRx will be eligible to receive up to $330 million in milestone payments tied to development progress and sales targets as well as tiered double-digit escalating to the mid-teens royalty payments contingent upon certain sales thresholds in the U.S. and a fixed royalty payment for markets outside the U.S.*
- *Agreement includes a right of first negotiation for new indications outside of the field of bipolar depression with suicidality for NRX-101 and/or potential new products containing D-cycloserine in combination with an antidepressant / antipsychotic*

RADNOR, Pa. and MORRISTOWN, N.J. and TAIPEI, Taiwan, June 05, 2023 (GLOBE NEWSWIRE) -- Lotus Pharmaceuticals (1795:TT; "Lotus"), a multinational pharmaceutical company, Alvogen, a privately owned U.S. based pharmaceuticals company, and NRx Pharmaceuticals Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals or NRx"), a clinical stage biopharmaceutical company, today announced a global collaboration agreement covering the development and commercialization of NRX-101 for suicidal treatment-resistant bipolar depression (S-TRBD) for global markets.

Under the terms of the agreement, relating to NRX-101 for the U.S. market, NRx is entitled to receive an initial payment of $10 million upon achieving both a successful read-out from the ongoing Phase 2b/3 clinical trial in S-TRB and completion of a Type B meeting with the U.S. Food and Drug Administration (FDA). NRx would receive an additional payment of $5 million upon receipt of FDA approval for NRX-101 as well as bonus milestone payments of increasing amounts up to $330 million based on reaching certain net sales targets. In addition to success-based payments, NRx is eligible to receive a royalty on net sales between 12% and 16% contingent on certain sales thresholds for the U.S. market and other success-based payments for markets outside of the U.S.

Lotus will acquire worldwide rights for NRX-101 for treatment of S-TRBD and will be responsible for commercialization of NRX-101 in markets outside of the U.S. through their direct commercial presence in certain Asian markets or through Lotus's export division where the company currently markets an extensive portfolio of products through top-tier partners. Lotus will partner with Alvogen, a longstanding partner for Lotus in the U.S., to commercialize NRX-101 for treatment of S-TRBD in the U.S. market through Alvogen's Almatica label. Almatica is the CNS-focused division of Alvogen that currently markets six branded products. Alvogen and Lotus have committed to fund the next registrational study in suicidal treatment-resistant bipolar depression to support approval of NRX-101 contingent upon successful results of the ongoing Phase 2b/3 clinical trial and completion of a Type B meeting with the FDA. Lotus and Alvogen will have a right of first negotiation for new indications outside of the field of bipolar depression with suicidality for NRX-101 and/or potential new products containing D-cycloserine in combination with an antidepressant / antipsychotic.

Stephan Willard, J.D., Chief Executive Officer of NRx, commented, “This collaboration can accelerate the delivery of NRX-101 to patients grappling with suicidal bipolar depression who desperately need better treatment alternatives. With our current resources we believe we can fund our operations until the expected Phase 2b/3 trial data. This global partnership significantly minimizes the need for future capital raises for NRX-101 development and commercialization. Alvogen and Lotus, with their CNS expertise and global operational capabilities, are ideal partners for this and possibly other NRx programs.”

Lisa Graver, Chief Executive Officer of Alvogen, commented, “A medication that improves depression in bipolar patients with elevated risk of suicide would represent a significant improvement in treatment, and we view the Phase 2 STABIL-B data of NRX-101 as promising to that effect. This agreement is congruent with our strategy of developing branded CNS products with clear differentiation and patient benefit while leveraging our proven commercialization capabilities under our Almatica brand. NRX-101 provides an excellent addition to our growing CNS pipeline.”

Petar Vazharov, Chief Executive Officer of Lotus, commented, “This is an exciting transaction for Lotus. Over much of the last decade, Lotus has been able to transition itself from a domestic generics Taiwanese company into a global pharma company that exports its intellectual property all over the world through either our direct presence across Asia or through our export business that includes the U.S., Japan, China, Latin America and Europe. The addition of NRX-101 to our pipeline is completely in-line with our strategic objective to drive heightened innovation that addresses significant unmet medical needs.”

An estimated seven million people are living with bipolar depression in the U.S. alone[1]. The risk of suicide within the group is very high, with data indicating that 50% or more of these patients will attempt suicide in their lifetime[2]. There are currently no medications specifically approved for people with bipolar depression and elevated levels of suicidality. NRX-101 is the first investigational medication to be specifically studied in this vulnerable patient population. Proof-of-concept data from the Phase 2 STABIL clinical trial, in which patients with bipolar depression and acute suicidality were randomized to NRX-101 or lurasidone after stabilization with one infusion of ketamine, showed a statistically significant benefit of NRX-101 vs lurasidone. Based on these data, the U.S. FDA granted Breakthrough Therapy Designation (BTD) and a Special Protocol Assessment (SPA) for NRX-101 in bipolar depression with acute suicidality.

NRx Pharma recently announced that it has upgraded and expanded its ongoing Phase 2 randomized, controlled clinical trial in bipolar depression with sub-acute suicidality to a registrational Phase 2b/3 clinical trial. Results from the ongoing Phase 2b/3 clinical trial are expected by year-end 2023. NRx will be hosting a conference call to discuss in greater detail the impact of the transaction.

About NRX-101

Up to 50% of individuals with bipolar disorder attempt suicide over their lifetime, and estimates indicate that up to 20% may succumb to suicide[3]. The only FDA-approved treatment for patients with treatment-resistant suicidal bipolar depression remains electroconvulsive therapy.

Conventional antidepressants can increase the risk of suicide in certain patients; hence their labels contain a warning to that effect. NRX-101 is a patented, oral, fixed dose combination of D-cycloserine and lurasidone, neither of which has shown addiction potential in preclinical models. Based on the results of a Phase 2 proof-of-concept study, NRX-101 received Breakthrough Therapy Designation from the FDA for the treatment of severe bipolar depression in patients with Acute Suicidal Ideation & Behavior (ASIB) after initial stabilization with ketamine or other effective therapy.

NRX-101 is one of the first oral antidepressants currently in late-stage clinical studies targeting the NMDA-receptor in the brain, which represents potentially a key new mechanism to treat depression with and without suicidality, as well as PTSD and other indications. To date, NRX-101 is the only oral NMDA investigational

medicine focused on bipolar depression in patients with acute and sub-acute suicidality.

About NRx Pharmaceuticals

NRx Pharmaceuticals is a clinical-stage biopharmaceutical company developing therapeutics for the treatment of central nervous system disorders, specifically bipolar depression with suicidality and post-traumatic stress disorder (PTSD). The company's lead program NRX-101, an oral, fixed-dose combination of D-cycloserine and lurasidone, targets the brain's N-methyl-D-aspartate (NMDA) receptor and is being investigated in a Phase 2b/3 clinical trial for Suicidal Treatment-Resistant Bipolar Depression, which includes patients with both acute and sub-acute suicidality, an indication for which the only approved treatment is electroshock therapy. The company's prior Phase 2 STABIL-B clinical trial evaluating NRX-101 in patients with Severe Bipolar Depression with Acute Suicidal Ideation & Behavior (ASIB) demonstrated a substantial improvement over available therapy in reducing depression and suicidality compared to placebo when patients were treated with NRX-101 after a single dose of ketamine. Based on the findings from the STABIL-B trial, the U.S. Food and Drug Administration (FDA) granted a Special Protocol Agreement and Breakthrough Therapy Designation for NRX-101 in patients with Severe Bipolar Depression with ASIB.

About Alvogen and Almatica

Alvogen is a privately held pharmaceutical company focused on developing, manufacturing and selling generic and branded products for the US market. The company has a diverse portfolio and pipeline that includes both branded and generic products across various administration forms. The Alvogen-family of companies includes Alvogen US (Generics), Almatica (Brands) and Almaject (Injectables).

Almatica Pharma LLC is a wholly owned subsidiary of Alvogen, Inc. and is a U.S. pharmaceutical company focused on the development, acquisition and commercialization of branded pharmaceutical products. Its current product portfolio covers a range of therapeutic areas, but promotional focus is on central nervous system disorders and conditions.

About Lotus

Founded in 1966, Lotus (1795: TT) is an international pharmaceutical company with global presence, focused on commercializing novel and generic pharmaceuticals, offering patients better, safe and more accessible medicines. The Company has a recognized best-in-class R&D and manufacturing platform in Asia and has established partnerships in nearly every global market including the U.S., Europe, Japan, China, and Brazil. Lotus runs over 100 strategically selected pharmaceutical projects in development and registrations across Asia and the US, with over 250 commercial products. The Company invests in diversified best portfolio consisting of high-barrier oncology, complex generics as well as 505(b)2 and NCE via internal R&D investment and licensing-in partnership, and also strengthens its portfolio competitiveness by adding biosimilar products with support from strategic partners. Its industry-leading infrastructure certified by most of the advanced regulatory authorities around the world, including US FDA, EU EMA, Japan PMDA, China FDA, and Brazil ANVISA.

[1]Merikangas, K., et al.(2007). Lifetime and 12-Month Prevalence of Bipolar Spectrum Disorder in the National Comorbidity Survey Replication. Arch Gen Psychiatry, 64:543-552

[2]Pallaskorpi, et al. Incidence and Predictors of suicide attempts in bipolar I and II disorder: A 5-year follow-up study, Bipolar Disorders, 2016

[3]Psychiatric Times; Suicide Attempts and Completions in Patients with Bipolar Disorder

NRX Cautionary Note Regarding Forward-Looking Statements

This announcement of NRx Pharmaceuticals, Inc. includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995, which may include, but are not limited to, statements regarding our financial outlook, product development, business prospects, and market and industry trends and conditions, as well as the Company's strategies, plans, objectives, and goals. These forward-looking statements are based on current beliefs, expectations, estimates, forecasts, and projections of, as well as assumptions made by, and information currently available to, the Company's management.

The Company assumes no obligation to revise any forward-looking statement, whether as a result of new information, future events or otherwise. Accordingly, you should not place reliance on any forward-looking statement, and all forward-looking statements are herein qualified by reference to the cautionary statements set forth above.

Lotus Cautionary Note Regarding Forward-Looking Statements

Except for historical information contained herein, the matters set forth in this document are forward looking statements that are subject to risks and uncertainties that could cause actual results to differ materially. These forward-looking statements are not based on historical facts but rather on management’s expectations regarding future growth, results of operations, performance, future capital and other expenditures, competitive advantages, business prospects and opportunities. Statements in this presentation about our future plans and intentions, results, level of activities, performance, goals or achievements or other future events constitute forward looking statements. Wherever possible, words such as “anticipate”, “believe”, “expect”, “may”, “could”, “will”, “potential”, “intend”, “estimate”, “should”, “plan”, “predict”, or the negative or other variations of statements reflect management’s current beliefs and assumptions and are based on the information currently available to our management. Investors are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this document and we assume no obligation to update or revise any forward-looking statements.

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